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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,837	03/17/2004	Ellen M. Beasley	CL001229-DIV	4092

25748 7590 09/29/2006

CELERA GENOMICS
ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY
45 WEST GUDE DRIVE
C2-4#20
ROCKVILLE, MD 20850

EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,837	BEASLEY ET AL.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 24-35* is/are pending in the application.

4a) Of the above claim(s) *1,2,37 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 24-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Election/Restriction:

1a. Applicant's election with traverse of the invention of Group III (original claim 3 and new claims 24-38), drawn to an isolated antibody that selectively binds to the polypeptide of SEQ ID NO:3, filed on 05 September 2006 is acknowledged.

Applicants' traversal is on the grounds that examination of the antibody claims of Group III which selectively binds to the polypeptide of Group I is based in part on search and examination of the amino acid sequence of the polypeptide of Group I. Therefore, because the search and examination necessary to examine the claims of group III, inherently includes a search and examination of the Group I polypeptide, Applicants request that inventions of Group I and Group III be searched and examined.

As was set forth in the restriction requirement mailed on 03 August 2006, although the inventions of both Group I and Group III are polypeptides, the polypeptide of Group I is a single chain molecule that functions as a cytokine, whereas the polypeptide of Group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of Group I and the antibody of Group III are structurally distinct molecules; any relationship between a polypeptide of Group I and an antibody of Group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

Furthermore, the polypeptide of Group I could potentially contain numerous regions to which an antibody may bind, whereas the antibody of Group III is defined in terms of its binding specificity to a small structure within SEQ ID NO: 3. Therefore the polypeptide and antibody are patentably distinct. Moreover, searching the inventions of Group I and Group III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Group III. Moreover, antibodies which bind to an epitope of a polypeptide of Group I may be known even if a polypeptide of Group I is novel. In addition, the technical literature search for the polypeptide of Group I and the antibody of Group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The restriction requirement is still deemed proper and is therefore made FINAL.

Status of Claims:

1b. Original claims 1-3 and new claims 24-38 are pending, of which claims 3 and 24-36 are drawn to the elected invention, and will be searched and examined. Claims 1-2, 37 and 38 are withdrawn from consideration by the Examiner as they are drawn to non-elected invention.

1c. Claims 4-23 have been cancelled and new claims 24-38 have been added with the current response (05 September 2006).

Specification:

2a. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

2b. This application appears to be a division of Application No. 09/841,158, filed 25 April 2001. A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in an earlier or parent application is known as a divisional application or "division." The divisional application should set forth the portion of the earlier disclosure that is germane to the invention as claimed in the divisional application.

Claim rejections-35 USC § 102:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 3, 24-36 are rejected under 35 U.S.C § 102(a) as being anticipated by Ruben, SM (Accession Number: AAB58138; WO 20055180, published 21 September 2000).

The instant claims 3, 24-36 encompass an antibody that binds to a polypeptide, wherein said polypeptide consists or comprises the amino acid sequence set forth in SEQ ID NO:3, wherein said antibody is monoclonal, or coupled to a detectable substance, or fragments of said antibody or a composition comprising said antibody and a pharmaceutically acceptable carrier.

Ruben discloses an isolated polypeptide that shares 41.6% over all homology and 100% local homology from amino acid residue 1-120 to the polypeptide of SEQ ID NO:3 of the instant Application. See attached copies of the comparison of SEQ ID NO:3 of the instant invention and the sequence of the reference (SEQUENCE COMPARISON 'A'). Ruben also discloses an antibody that binds to his polypeptide, said antibody which is monoclonal, coupled to detectable label, a fragments of said antibody and a composition comprising said antibody and a heterlogous polypeptides, and methods of producing said antibody, (see pages 187-189, also see SEQ ID NO:476).

The antibody disclosed by Ruben would be expected to bind to a polypeptide which consists or comprises the amino acid sequence set forth in SEQ ID NO:3, because an antibody binds to an epitope of six consecutive amino acid residues and the polypeptide disclosed in the cited reference comprises at least 120 consecutive amino acid residues as SEQ ID NO:3.

Therefore, Ruben anticipates instant claims 3, 24-36 in the absence of any evidence to the contrary.

Claim rejections-35 USC § 103:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 3, 24-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruben, SM (Accession Number: AAB58138; WO 20055180, published 21 September 2000) and Platica et al (10 September 1999).

The instant claims 3, 24-36 encompass an antibody that binds to a polypeptide, wherein said polypeptide comprises the amino acid sequence set forth in SEQ ID NO:3, wherein said antibody is monoclonal, or coupled to a detectable substance, or fragments of said antibody or a composition comprising said antibody and a pharmaceutically acceptable carrier.

Platica et al teach a human transcobalamin II precursor polypeptide that shares 97.5% over all homology to the polypeptide of SEQ ID NO:3 of the instant Application. See attached copies of the comparison of SEQ ID NO:3 of the instant invention and the sequence of the reference (SEQUENCE COMPARISON 'B'). However, Platica et al reference does not teach an antibody that binds to the polypeptide it discloses.

As discussed above in section 3, Ruben teaches antibodies and methods of making said antibodies.

It would have been prima facie obvious to the person of ordinary skill in the art at the time the invention was made to make antibodies and fragments of antibodies that

bind to the polypeptides taught by Platica et al, using methods taught by Ruben. An antibody produced against the polypeptide of Platica et al would be expected to bind to a polypeptide which consists or comprises the amino acid sequence set forth in SEQ ID NO:3, because an antibody binds to an epitope of six consecutive amino acid residues and the polypeptide disclosed in the reference comprises more than 6 consecutive amino acid residues of SEQ ID NO:3. The skilled artisan would be motivated to produce antibodies against the polypeptide taught by Platica et, because the advantages of doing so is discussed by Ruben, and there would be a reasonable expectation of success, since making and using these types of antibodies have been widely and successfully used in the field of immunology. Furthermore, one of ordinary skill in the art would have been motivated to formulate said antibody in a pharmaceutically acceptable carrier, following the method taught by Ruben, because the human transcobalamin II precursor taught by Platica et al is a physiologically relevant protein as it is the primary transport protein for vitamin B12.

Conclusion:

5. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud
Patent Examiner
Art Unit 1647
25 September 2006

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER